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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,355	03/15/2004	Thomas S. Wilson	IL-11176	3229

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EXAMINER	
SONNETT, KATHLEEN C	
ART UNIT	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

ED

Office Action Summary	Application No.	Applicant(s)	
	10/801,355	WILSON ET AL.	
	Examiner	Art Unit	
	Kathleen Sonnett	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/15/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims (1, 2), 3, 4, 5, 8, 45, and 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims (1), 4, 10, 11, 18, 19, and 23 of copending Application No. 10/781,582 (as amended in the last filed amendment to the claims on 12/13/06. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims of copending Application No. 10/781,582 is narrower and therefore anticipates the broader claims of the instant application (1-5 and 8).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5-7, 12-15, 21, 23, 24, 27-29, 34- 37, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Maitland et al. (2002/0095169). Maitland et al. discloses an apparatus for occluding a physical anomaly comprising a shape memory polymer for positioning in the interior of the physical anomaly and a system for providing the shape memory polymer with a primary shape for occluding the physical anomaly and a secondary shape for being positioned in interior of the physical anomaly (see abstract).

Regarding claims 5-7 and 27-29, the apparatus includes a delivery catheter (30) and a guide wire (32). The shape memory material is at the end of the guide wire.

Regarding claims 12, 13, 34, and 35, Maitland et al. discloses a system for providing the shape memory material with a primary and secondary shape comprising a system for optical heating using optic fibers to transport light (laser) energy to the shape memory material body through the optical fiber (see [0059], [0062]).

Regarding claims 14 and 36, the optical fiber may be multimode ([0061]).

Regarding claims 15 and 37, the shape memory material comprises a light absorbing material ([0059]).

Regarding claims 21 and 43, the shape memory material has a primary shape that is larger than a secondary shape (see fig. 1 and 2).

Claims 1, 2, 5-7, 21, 23, 24, 27-29, 43, 45, and 47 arerejected under 35 U.S.C. 102(b) as being anticipated by Kamiya et al. (U.S. 5,192,301). Kamiya et al. discloses an apparatus for

occluding a physical anomaly comprising a shape memory polymer for positioning in the interior of the physical anomaly and a system for providing the shape memory polymer with a primary shape for occluding the physical anomaly and a secondary shape for being positioned in interior of the physical anomaly (see abstract).

Regarding claims 5-7 and 27-29, the apparatus includes a delivery catheter (22) and a guide wire (23). The shape memory material is at the end of the guide wire (see fig. 27).

Regarding claims 21 and 43, the shape memory material has a primary shape that is larger than a secondary shape (see abstract). This is capable of occluding an anomaly.

Regarding claims 45 and 47, Kamiya et al. discloses a method of occluding a physical anomaly, the physical anomaly having an interior comprising the steps of providing a shape memory material body with a secondary shape for being positioned in the interior of a physical anomaly, positioning the body in the anomaly when in its secondary shape, and causing the body to change to a larger primary shape for occlusion (see abstract). A catheter is used to position the shape memory body in the interior of the anomaly in its secondary shape (see col. 7 ll. 66-col. 8 ll. 30).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 22, 25, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya et al. in view of Bleys et al. Kamiya et al. disclose the invention substantially as stated above, but fail to disclose that the shape memory polymer is foam.

Foams are well known in the art for forming occlusions or sealing holes in the body to ensure that liquid cannot escape. Bleys et al. discloses foam that has shape memory properties, is flexible, and has a minimum amount of leachable substances, which makes the foam especially useful in medical applications. It would have been obvious to one of ordinary skill in the art to modify the device of Kamiya et al. to choose the shape memory foam of Bleys et al. for the shape memory material body because of its biocompatibility (col. 6 ll. 45-51).

Claims 3, 8-11, 22, 25, 30-33, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maitland et al. in view of Bleys et al. Maitland et al. disclose the invention substantially as stated above, but fail to disclose that the shape memory polymer is foam.

Foams are well known in the art for forming occlusions or sealing holes in the body to ensure that liquid cannot escape. Bleys et al. discloses foam that has shape memory properties, is flexible, and has a minimum amount of leachable substances, which makes the foam especially useful in medical applications. It would have been obvious to one of ordinary skill in the art to modify the device of Maitland et al. to choose the shape memory foam of Bleys et al. for the shape memory material body because of its biocompatibility (col. 6 ll. 45-51).

Regarding claims 8-10 and 30-32, Maitland et al. discloses a system for providing the shape memory body with a primary and secondary shape comprising electromagnetic energy delivered optically (which is a form of radiation) (see [0057]).

Regarding claims 11 and 33, modified Maitland et al. discloses a shape memory polymer foam connected at the end of the guidewire (see fig. 7).

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Claims 17-20 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya et al. or Maitland et al. in view of Porter (US 2002/0165582). Kamiya and Maitland et al. both disclose the invention substantially as stated above, but fail to disclose that the

system for providing the shape memory material with two different shapes comprises microparticles or nanoparticles that can selectively absorb RF radiation converting it to heat.

However, Porter discloses that it is old and well known to provide microparticles in a substance used to fill any site in the human body ([0011], [0018], [0085]). These particles selectively absorb RF radiation, converting it to heat. The shape memory polymer of Maitland et al. is heated to cause the shape memory polymer to change shape and providing the microparticles of Porter would provide an advantageous means of heating because the small magnetic particles are a point heat source and do not cause significant tissue damage around the implantation site [0082]. Kamiya et al. is silent regarding how the shape memory body is heated and the disclosure of Porter teaches an appropriate method to achieve such heating of the device. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Maitland et al. or Kamiya et al. to include magnetic microparticles as made obvious by Porter in order to have a convenient point heat source and the use of a shape memory material with a higher transition temperature.

Regarding the use of nanoparticles, applicant has not disclosed that nanoparticles are used for any particular purpose, provide any advantage or solve a particular problem as compared to the use of microparticles. Furthermore, it would appear to one of ordinary skill in the art that the instant device and modified Maitland et al. would perform equally well with the claimed nanoparticles or the microparticles as taught by Porter. Therefore, it would be prima facie obvious to use the claimed nanoparticles instead of the microparticles because they are considered an obvious design choice that fails to patentably distinguish over the prior art of Maitland et al. in view of Porter.

Claims 46 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya et al. in view of Bleys et al. Kamiya et al. discloses the method substantially as stated above, but fail to disclose that the shape memory polymer that is provided is foam.

Foams are well known in the art for forming occlusions or sealing holes in the body to ensure that liquid cannot escape. Bleys et al. discloses foam that has shape memory properties, is flexible, and has a minimum amount of leachable substances, which makes the foam especially useful in medical applications. It would have been obvious to one of ordinary skill in the art to modify the device of Kamiya et al. to choose the shape memory foam of Bleys et al. for the shape memory material body because of its biocompatibility (col. 6 ll. 45-51).

Regarding claim 49, the shape memory body is connected at the end of a guidewire (fig. 27 or 28 of Kamiya).

Claims 48-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya et al. in view of Maitland et al. Kamiya et al. discloses the method substantially as stated above, but fails to disclose using a laser and optical fiber to transmit laser light through the optical fiber.

However, Maitland et al. discloses that it is old and well known in the art to use optical fibers and lasers to heat a shape memory polymer such that it takes a larger primary shape. Kamiya et al. discloses that the plug is warmed to change shape but is silent on how this is achieved and Maitland et al. provides a heating method that does will not cause trauma to the surrounding tissue. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Kamiya et al. to include using an optical fiber and laser to transmit laser light through the optical fiber to heat the shape memory body without causing surrounding trauma.

Claims 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya et al. in view of Porter. Kamiya et al. discloses the method substantially as stated above, but

fails to disclose providing a shape memory material body that has microparticles or nanoparticles of a material which can selectively absorb RF radiation converting it to heat.

As mentioned above, Kamiya is silent on how the shape memory body is warmed and Porter teaches the use of magnetic microparticles dispersed in a polymer that can selectively absorb RF radiation converting it to heat. These microparticles provide point sources of heat that do not cause significant tissue damage around the implantation site [0082]. Providing such a system in the body of Kamiya et al. would allow the use of materials with transition temperatures further away from body temperature without damage to tissue. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Maitland et al. or Kamiya et al. to include magnetic microparticles as made obvious by Porter in order to have a convenient point heat source and to be able to use of a shape memory material with a higher transition temperature.

Regarding the use of nanoparticles, applicant has not disclosed that nanoparticles are used for any particular purpose, provide any advantage or solve a particular problem as compared to the use of microparticles. Furthermore, it would appear to one of ordinary skill in the art that the instant device and modified Maitland et al. would perform equally well with the claimed nanoparticles or the microparticles as taught by Porter. Therefore, it would be prima facie obvious to use the claimed nanoparticles instead of the microparticles because they are considered an obvious design choice that fails to patentably distinguish over the prior art of Maitland et al. in view of Porter.

Claims 4 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya et al. or Maitland et al. Kamiya et al. and Maitland et al. each disclose the invention substantially as stated above, but fail to disclose that that the shape memory material body is biodegradable. However, it is very well known in the medical arts to make occlusion devices

biodegradable such that surrounding tissue can grow into and eventually replace the device. Therefore, it would have been obvious to one of ordinary skill in the art to modify the inventions of Kamiya et al. or Maitland et al. such that the body is biodegradable.

Claims 16 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maitland et al. Maitland et al. discloses the invention substantially as stated above including that the shape memory material body comprises a light absorbing material. Maitland et al. fails to expressly disclose that the shape memory material comprises a light absorbing dye in an elastomeric coating. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide a light absorbing elastomeric coating instead of a light absorbing material because Applicant has not disclosed that the coating provides an advantage, is used for a particular purpose, or solves a stated problem over the use of a light absorbing material. One of ordinary skill in the art, furthermore, would have expected Maitland's material and applicant's invention, to perform equally well with either the material taught by Maitland et al. or the claimed coating because both perform the same function of absorbing light equally well.

Therefore, it would have been prima facie obvious to modify Maitland et al. to obtain the invention as specified in claims 16 and 38 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Maitland et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 2/26/2007

GLENN K. DAWSON
PRIMARY EXAMINER